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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
WEBB, SARAH K

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/872,640	Applicant(s) SIRHAN ET AL.	
	Examiner Sarah K Webb	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/13/2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Drawings

1. The corrected or substitute drawings were received on August 13, 2001. These drawings are accepted by the draftsman.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 46 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to whether applicant is trying to form a dependent claim with "as in claim 15" on line 4, or is referring to a method in claim 15 (which does not exist).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined

was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-3, 7,13,15-18,23,25,29-31,37,38, and 40 - 45 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,820,595 to Parodi.

Parodi includes a catheter (150) having distal and proximal ends, a guidewire lumen (190), guidewire (162), and balloon (180) receivable over the catheter body. (see Figure 1). As shown in Figures 4-6, the catheter body (154) has three lumens (190,191,192), and the perimeter is circular. The catheter includes multiple tubes coupled together, as most clearly illustrated in Figures 2 and 3. Referring to claim 13, Parodi discloses that the inflation lumen (191) for the distal balloon (170) mates with inlet port (193) (column 5, line 30). The catheter of Parodi allows for a balloon to slide along its proximal end, as the balloons were designed to be slidable for adjusting purposes. Figures 7 and 8 illustrate expandable prostheses disposed over both the first and second balloons. Figure 1 shows a second balloon slidably attached to the catheter by way of a passage. Figure 3 illustrates the embodiment of claim 23, where an inflatable balloon (180) is disposed over a moveable sleeve (202). The sleeve (202) is slidable over the catheter (154). This embodiment is also described in lines 44-61 of column 6. In line 8 of column 7, Parodi explains that the catheter (150) includes a prosthesis (350) and is shown in Figures 7-9. Referring to claim 37, the tubular sleeve member, or catheter, has a passage, which is slidably receivable over the catheter body.

Regarding claims 38, 40-45, Parodi anticipates the claimed method including a proximal balloon, distal balloon, expanding both balloons, prosthesis carried by a balloon, and the inflation medium delivered through a lumen (column 5, line 30). The method is best described from line 60 of column 8 through line 11 of column 9. The inflation tube is formed by the catheter, which is connected to the balloon.

4. Claims 1-3,5,7,13,29, 36-40, and 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,836,967 to Schneider.

Schnieder shows a catheter that includes a guidewire (44), lumen (32), two balloons (14 & 26), fluid ports (40), and a rounded or "atraumatic" distal tip (46). Figure 2 illustrates that the catheter includes multiple lumens and has a circular perimeter. Figure 2 also shows that the catheter consists of multiple tubes coupled together. Lumen (30) serves as an inflation lumen by supplying pressurizing medium to the balloon (column 3, line 25). Regarding claim 37, Schneider explains that an inner catheter is inside a passage of an outer catheter (column2, lines 44-50).

Regarding claims 38-40 and 43-45, Schneider explains the method of using the catheter assembly that includes distal and proximal balloons, expanding both balloons by way of an inflation medium and lumen. Figure 1 shows that the balloon structures are different, and Schneider explains that one balloon may be configured as a dilation balloon (column 2, line 62).

5. Claims 1-9,12-14,19,21,22 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No.5,458,613 to Gharibadeh et al.

Gharibadeh has a catheter with guidewire (28), guidewire lumen (14), inflatable balloon (13) with catheter passage, a circular perimeter, an atraumatic tip (29), multiple tubes coupled together, an inflation lumen (12), and an inflation tube (21) formed of high strength material (col 6, line 35). The catheter body (11) can be formed from polymers or composite materials (col 8, lines 53-56). The catheter body includes an axial slit (24) over a portion of the guidewire lumen (col 3, line 42). The inflation tube serves as a *deployment shaft* for the balloon, and the axial slit could be configured to receive a different tube.

Referring to claim 4, ratios and Figure 1 were used to determine if the catheter of Gharibadeh includes a distal taper at least 3 mm long. Figure 7 is about 5 times larger than actual size (guidewire dimensions used to determine ratio), and the taper measured from the picture is about 2mm. 5 times 2 mm equals 10 mm, which satisfies the limitation of at least 3 mm.

Regarding claim 12, Gharibadeh explains that the catheter shaft (11) has a length within the range 100 – 150 cm (col 9, line 15). The inflation tube would then fall within the range of 10-150 cm.

Regarding claim 22, Gharibadeh explains that the catheter length has a range of 100-150 cm, which falls within the range of 50-200 cm. The guidewire lumen diameter should be (0.025-0.127 mm) larger than (0.2-0.89 mm), so this also falls within the claimed range of 0.2-2 mm. *(see col 9, first paragraph for further explanation of sizes).* Using the guidewire lumen sizes set forth above and Figure 4, one can see that the catheter outer diameter falls within the range of 1-5 F, or 0.33 mm – 1.65 mm.

6. Claims 1-3,8,13,16,19,20,21, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,416,529 to Holman et al.

Holman includes a catheter (12), guidewire and lumen, a balloon (22) slidable over the catheter, and a circular perimeter, in which the elements are most clearly illustrated in Figures 1,2, and 5. Figure 20 shows that a stent (124) may be placed over the balloon (122). An inflation lumen is included for inflating the balloon (col 7, line 61). Figures 43 and 44 show an inflation tube. Holman includes an axial slit or spiral slit on any of the tubular members, which would include the catheter body (col 8, paragraph 5). Holman explains, *"Any self-expanding stent or balloon expandable stent may be used with this invention"* (col 16, paragraph 6).

7. Claims 1-3,7,17, 34,36,38,40,44,45 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No.5,462,529 to Simpson et al.

Simpson includes a catheter device with two expandable balloons(20 and 48), a guidewire, multiple lumens (24,36, and 52), and atherectomy elements (38) coupled at the distal end of the catheter. Multiple catheters (12,28,40) are coupled together and have a circular cross section (Figure 2). In line 62 of column 6, Simpson explains that an infusion port may be included. The fourth paragraph of column 9 describes the treatment method, which includes positioning both distal and proximal balloons and expanding the balloons.

8. Claims 1,8,26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,989,281 to Barbut et al.

Barbut shows a catheter with an embolic capture element, or filter (220), attached to an expandable balloon (230) in Figure 4. An inflation tube (262) for the balloon is provided. Figure 1 shows the filter at the distal tip of the catheter, so this is within 20 cm of the distal end of the catheter. The balloon has a slidable passage received over the catheter.

9. Claims 1,28,31-33 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,264,671 to Stack et al.

Stack shows all the limitations of the claimed invention, as most illustrated in Figure 2d. The catheter includes a guidewire (200) and lumen, balloon (212), and self-expanding stent (320). The stent is both distal the balloon and partially under the balloon in an unexpanded state.

10. Claims 1 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,865,801 to Houser.

Houser includes a catheter (12), expandable balloon (24), guidewire (16), and guidewire lumen (col 4, line 43). The pressure sensing means is most clearly illustrated in Figure 6 and described in the 4th paragraph of column 5.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gharibadeh in view of Holman et al.

Gharibadeh includes all the limitations of claims 10 and 11, except for a groove in the inflation tube that has a length in the range from 10 cm to 50 cm and an opening in the range of 0.001 in to 0.014 in. Holman teaches that a slit can be provided in any sleeve, or tube, of a catheter system (column 8, line 53), and the slits allow the tubes to conform to diameter changes (column 9, line 44), including changing the diameter to receive another tube. Gharibadeh teaches that the catheter shaft (11) has a length within the range 100 – 150 cm (col 9, line 15), so the inflation tube would then fall within the range of 10-150 cm. Thus, the slit in the inflation tube would also fall in this range. In Figures 32a and 32b, the slit (spiral here) is shown to have a wide range of opening sizes. Compressed, the slit is 0 in wide, and expanded, the slit is about 0.0369 in wide. (15 mm length was used for sleeve to determine ratio of slit size in Figure 32b). This range would encompass the claimed range. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a slit in the inflation tube of Gharibadeh, as taught by Holman, as this allows the tube to conform to a wide range of diameters.

13. Claims 1,23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parodi in view of Holman.

Parodi includes all the limitations of the claims, except for the specific dimensions of the balloon and sleeve. Holman teaches a balloon catheter with a sleeve adjacent the balloon. In line 43 of column 7, Holman uses a typical balloon length of

about 15 mm, or 1.5 cm. Holman also explains that stents are typically 1.5 cm long, and that the balloon should be about the same length (col 16, line 52). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a typical balloon length of 1.5 cm, as taught by Holman, for the balloon of Parodi. Using this dimension as an estimate for the size of the balloon of Parodi, one can see that the sleeve (202) is at least twice as long as the balloon in Figure 3 of Parodi. Therefore, the length of the inner sleeve of Parodi would be equal to or greater than 3 cm, which falls with the range 3-50 cm.

14. Claims 1,15, 46, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parodi in view of U.S. Patent No. 6,044,845 to Lewis.

Parodi includes the structure of the catheter, as discussed above. Parodi fails to provide a kit containing the catheter device and instructions for use. Lewis teaches a catheter kit comprising a container, instructions, and other system components useful for a certain procedure (column 6, paragraph 4 through column 7) (Figure 9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a kit and instructions, as taught by Lewis, for the catheter system of Parodi, in order to provide a more consumer friendly product.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- U.S. Patent No. 5,910,154 to Tsugita teaches a catheter with expandable balloon, filter, and stent

- U.S. Patent No. 4,655,746 to Daniels et al. teaches a catheter with multiple lumens, expandable balloon, and many dimensions claimed in the application
- U.S. Patent No. 6,156,055 to Theron teaches a catheter with two different balloons and stent
- U.S. Patent No. 6,379,345 to Constanz teaches balloon catheter kits, multiple lumens, and atherectomy elements
- U.S. Patent No. 6,398,792 to O'Connor teaches a catheter with two balloons, stent, filter, and transducers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 305-7554. The examiner can normally be reached on 8am-4:30pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Sarah K Webb
Examiner
Art Unit 3731

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August 15, 2002

Michael Milano
Supervisory Patent Examiner
Art Unit 3700

DAVID O. REIP
PRIMARY EXAMINER